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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/205,251	12/04/1998	IRVING K. ARENBERG	DURE-021	8010

82893 7590 09/29/2011

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	PAPER NUMBER
3763	

MAIL DATE	DELIVERY MODE
09/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/205,251	ARENBERG ET AL.	
	Examiner	Art Unit	
	THEODORE STIGELL	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *26,28,29,54-60,66-68,70-75 and 80-86* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *26,28,29,54-60,66-68,70-75 and 80-86* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/2011 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 26, 28-29, 54-60, 66-68, 70-75, and 80-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al. (WO 97/38698) in view of Tamada et

al. (See "The development of polyanhydrides for drug delivery applications") and further in view of Husmann et al. (See "Hearing Research, Round window administration of gentamicin; a new method for the study of ototoxicity of cochlear hair cells").

Manning discloses a method of delivering a therapeutic agent into the inner ear of a living subject (see at least the abstract) compromising providing a drug delivery unit comprising a carrier material (hyaluronic acid gel) and a therapeutic agent (see at least page 6, lines 12-23) combined therewith, wherein the carrier material provides for controlled release of the therapeutic agent from the drug delivery unit over time, wherein the drug delivery unit is delivered to the round window niche and placed against the round window membrane (see at least page 4, lines 8-21), wherein the therapeutic agent is released from the drug delivery unit, contacts the membrane and passes into the inner ear.

Manning discloses that the gel has a certain amount viscosity to remain in position against the round window membrane (see page 5, lines 24-26) but Manning does not teach that the drug delivery unit is configured as a one of the recited shapes in claim 71.

Tamada et al. discloses a biodegradable drug delivery unit comprising a carrier material (polyanhydrides or polyorthoesters) and a therapeutic agent (see page 316, lines 1-11), wherein the drug delivery unit is configured as a solid in at least the forms of a disk (see at least page 317, line 29), a wafer which can be considered at least pellet, disk, tablet, or plate (see pages 320, 325), and a pellet (see page 344). Tamada further teaches that the disclosed drug delivery units have similar biocompatibility to Gelfoam

(see page 346, lines 10-15) which is known to be useful in treating the middle and inner ears (see at least Husmann for evidence). Tamada teaches that the disclosed drug delivery units provide the benefits of localized drug delivery, controlled and steady release rates, biodegradability, and the delivery of a wide range of therapeutic agents (see at least page 316, lines 1-11). Tamada discloses a drug release mechanism that is at least the equivalent of the drug release mechanism of Manning and possibly a mechanism that provides more benefits in terms of release rates and therapeutic agent compatibility.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Manning with the use of the drug delivery unit as disclosed by Tamada as the drug delivery unit of Tamada is at least the equivalent of Manning's drug delivery unit and could possibly provide more benefits. The references are analogous in that they both describe drug delivery units that are biocompatible for the middle and inner ear and therefore the combination is proper. The examiner notes that Manning only teaches away for solid drug delivery units made of hyaluronic acid but does not teach away for all solid drug delivery units. Tamada teaches solid drug delivery units with excellent drug delivery profiles and therefore the ordinary skilled artisan would not be deterred from using such a unit.

While Manning and Tamada teach practically all of the limitations recited in claim 71, they do not technically teach that it is known to deliver a solid drug delivery unit to the middle and inner ear. Husmann discloses a method of delivering solid pieces of Gelfoam to the round window niche and therefore shows it is known to deliver solid drug

delivery units to the middle and inner ears. It therefore would have been obvious to the ordinary skilled artisan to deliver the solid drug delivery unit of Tamada (which has the same biocompatibility as Gelfoam) into the round window niche to treat the inner ear as disclosed by Manning.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THEODORE STIGELL whose telephone number is (571)272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Theodore J Stigell/
Primary Examiner, Art Unit 3763